Packaging Protocols for Medical Temperature Sensitive Products requiring Storage Temperatures between 2^{o} C - 8^{o} C (36^{o} F - 46^{o} F)

IMPORTANT NOTICE!!

DD Forms 1502-1 and 1502-2
SHALL NOT BE USED
with these protocols.

Table of Contents

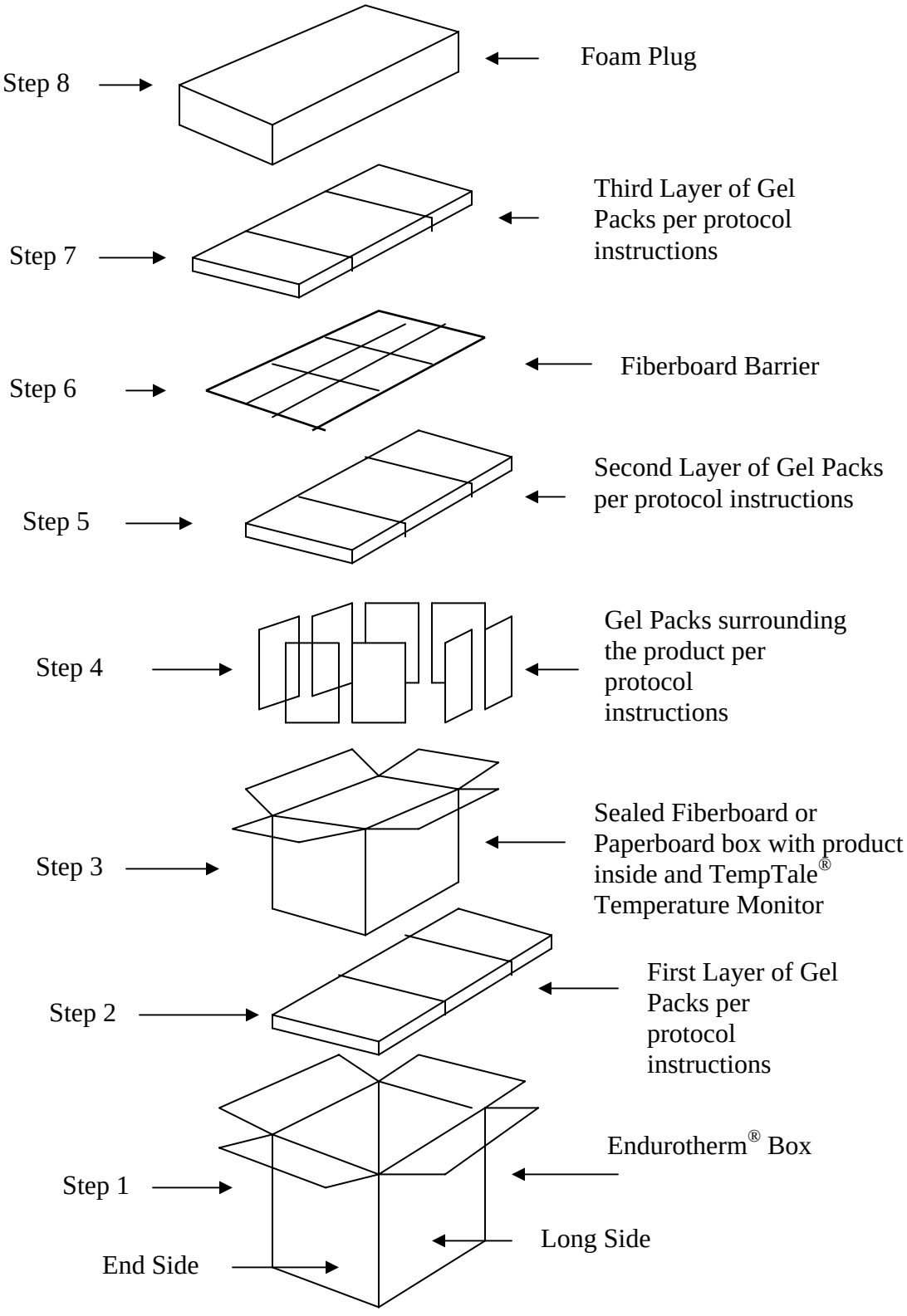
Page

Packaging Protocols:

TempTale®4 Procedures:

ISC Endurotherm® Box Packing Steps

The packing or layering of the Endurotherm® boxes is the same in principle for all four sizes (extra large, large, medium and small).



Cold Weather Packaging Protocol

- Cold Weather Configuration is used when the ambient temperature at the **receiving site** is consistently below 55° F.
- Protocols are designed to keep temperature-sensitive products requiring refrigeration temperatures between 2° C and 8° C (36^{o} F and 46^{o} F) within these temperature ranges during transportation, for up to 72 hours.
- 48 oz. and 24 oz. gel packs are used in all boxes for layering and void space filler.
- Coolant material must be placed in layers according to attached diagrams.
- Cold Weather configurations only use refrigerated gel packs. (See cold weather packing configuration diagrams.)

Cold Weather Packaging Protocol Procedures

The Cold Weather Packaging Protocol is used whenever the ambient or outside temperature at the receiving site consistently remains below 55 degrees Fahrenheit. Begin the cold weather packaging protocol by:

- Placing a layer of refrigerated gel packs at the bottom of the box.
- Next item will be the product.
- Place gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.
- This is followed by placing an activated TempTale®4 electronic temperature monitor on top of the product. Activate the TempTale®4 temperature monitor by pressing and releasing the "start" button. Once the button is released, a "sunshine" icon will appear in the upper left corner of the LCD. This indicates that the monitor is running. Peel off the tape in the back of the TempTale®4 and place it centered on top of the product.
- Follow with another layer of refrigerated gel packs.
- Above the second layer of refrigerated gel packs insert a fiberboard barrier.
- Add a final layer of refrigerated gel packs above the fiberboard barrier.
- Finally, insert the foam plug to seal the contents of the box.

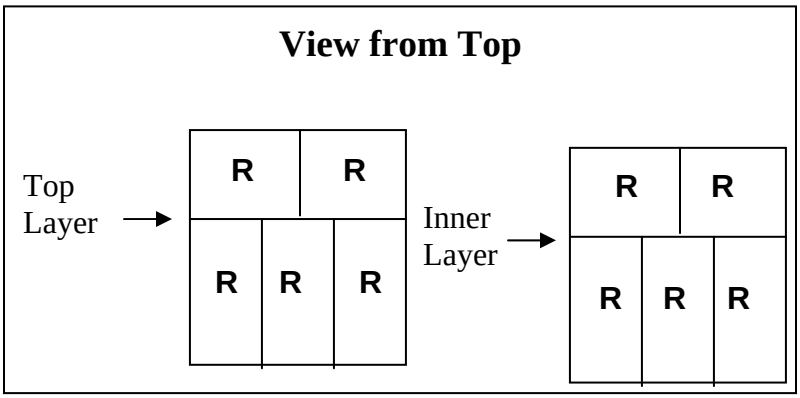
Notes:

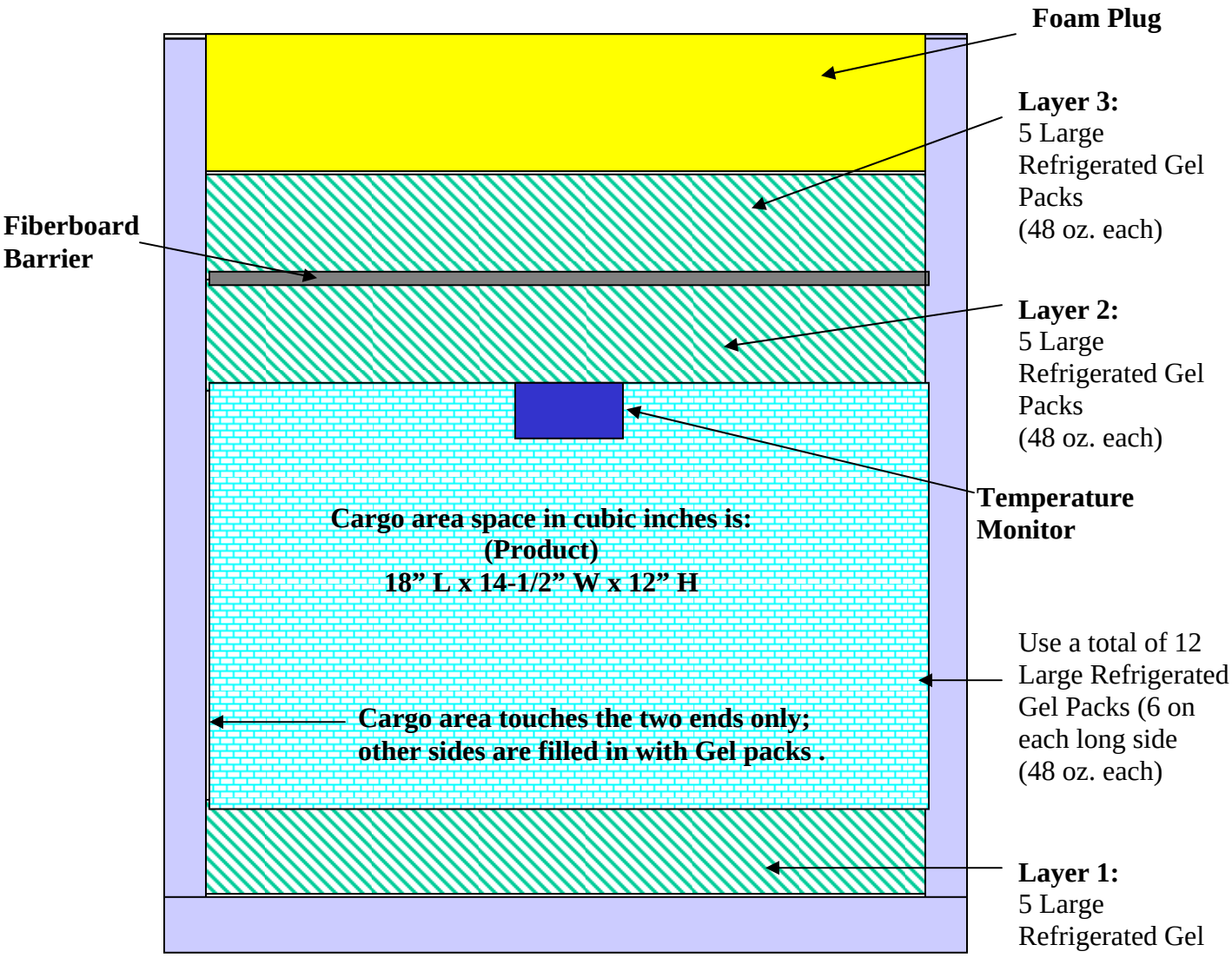
1. Follow procedures according to each protocol diagram of ISC Endurotherm® box used.
2. To chill large amounts of gel packs at once, place gel pack boxes inside a refrigerator that has been set to 4° C for at least 30 days prior to use.
3. To quickly chill small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior use.

Extra Large (ISC Box, E-327) – Cold Weather Packaging Protocol Diagram

Box Outer Dimensions:
24" x 24" x 24"
Refrigerant Pack Weight: 81 lbs
See attachment 3 for additional information.

Total amount of chilled Gel Packs = 27
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



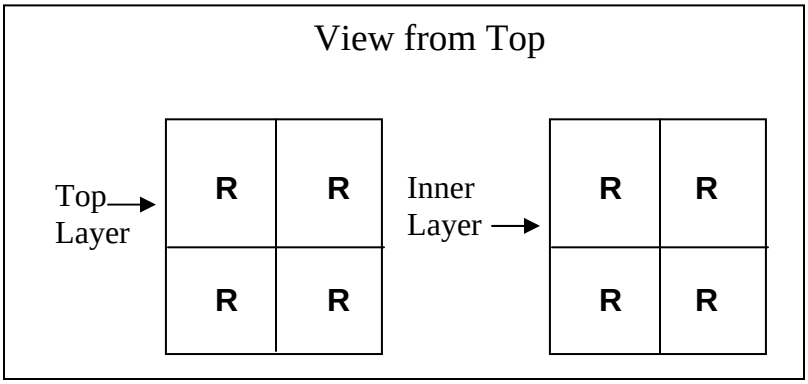


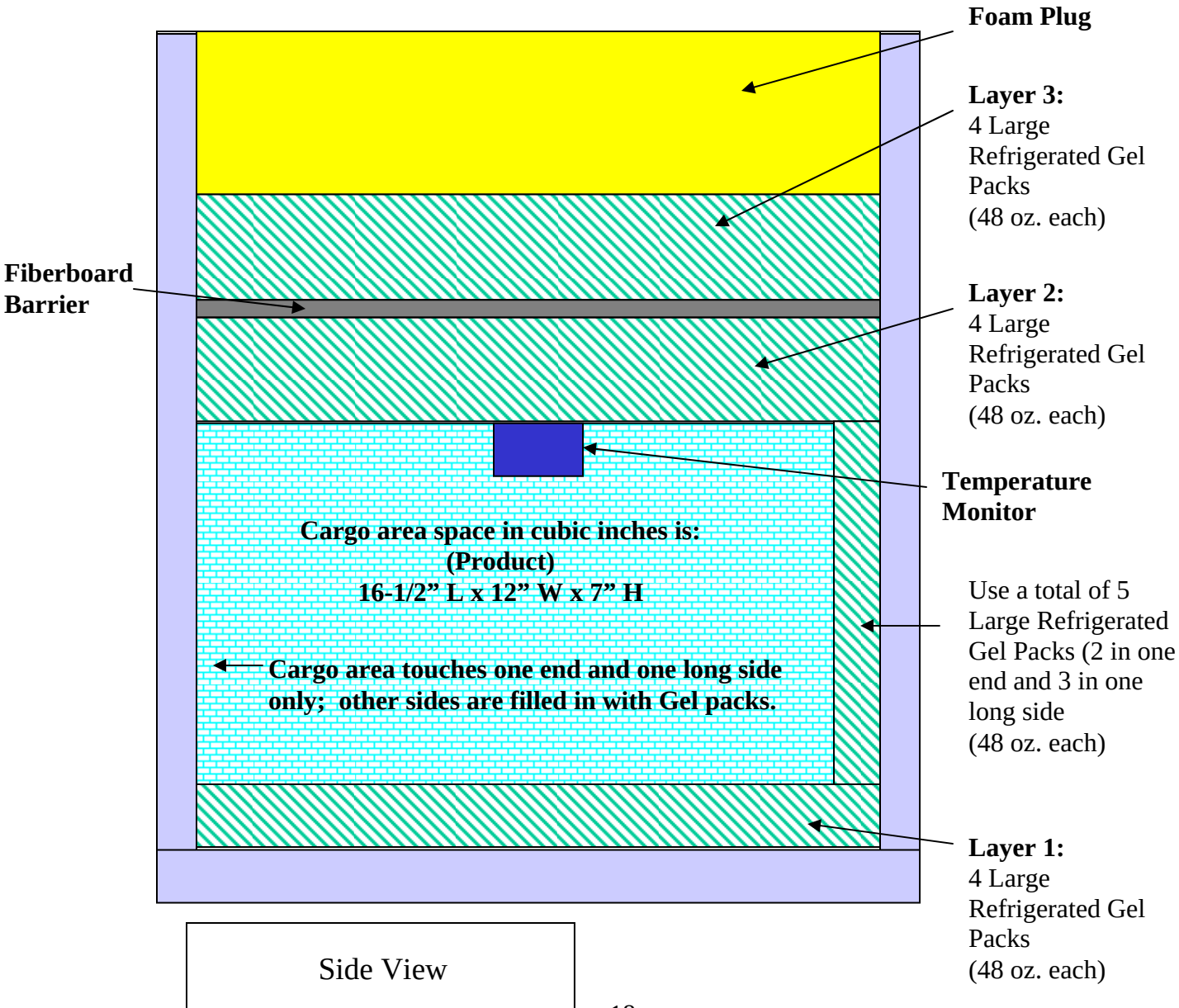
Side View

Large (ISC Box, E-186) – Cold Weather Packing Protocol Diagram

Box Outer Dimensions:
22-1/2" x 19" x 17-1/2"
Refrigerant Pack Weight: 51 lbs
See attachment 3 for additional information.

Total amount of chilled Gel Packs = 17
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs





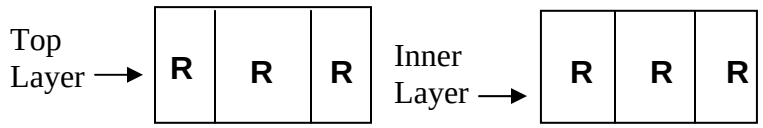
Side View

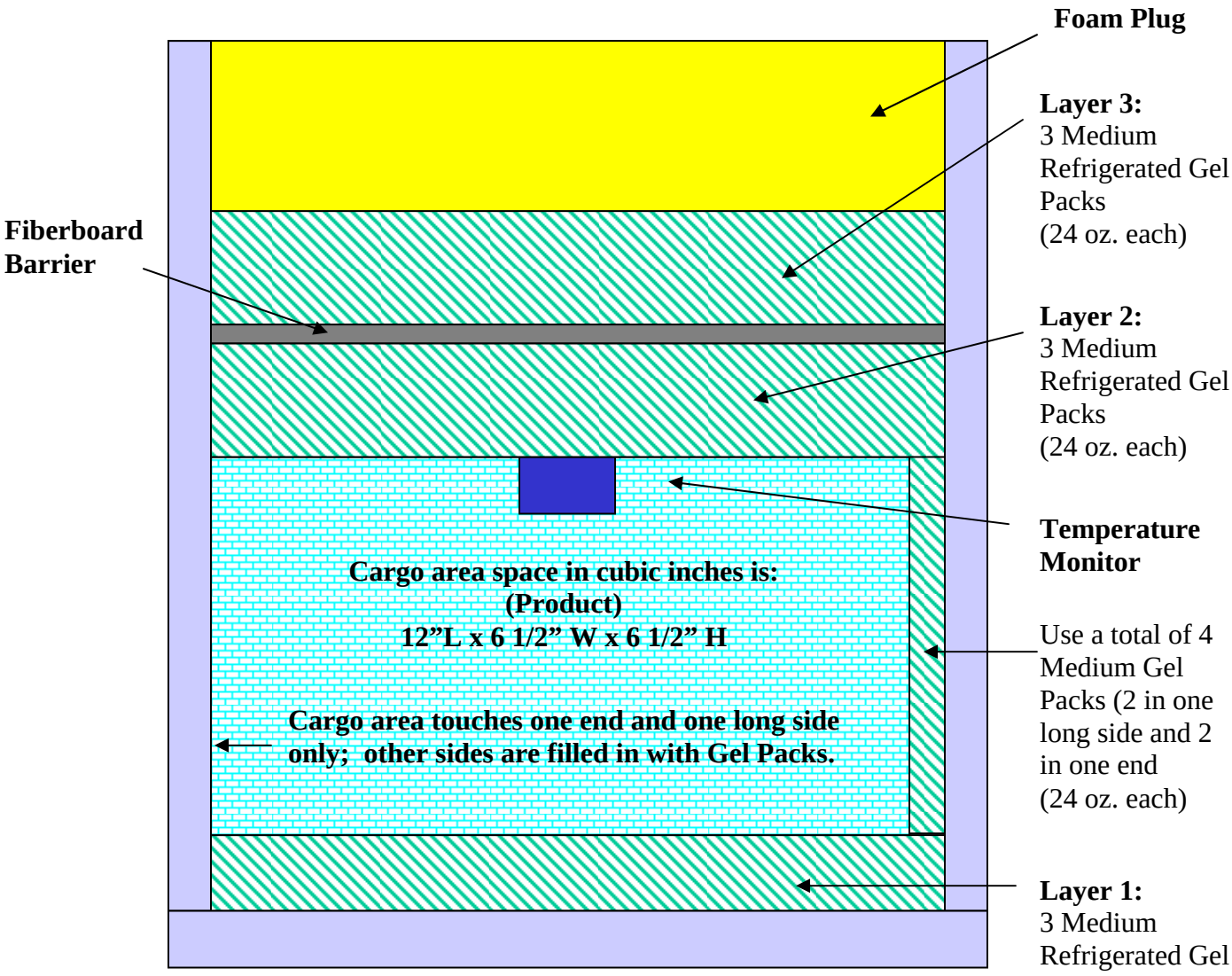
Medium (ISC Box, E-65) – Cold Weather Packing Protocol Diagram

Box Outer Dimensions: 18" x 12" 18"
Refrigerant Pack Weight: 19-1/2 lbs
See attachment 3 for additional information.

Total amount of chilled Gel Packs = 13
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs

View from Top



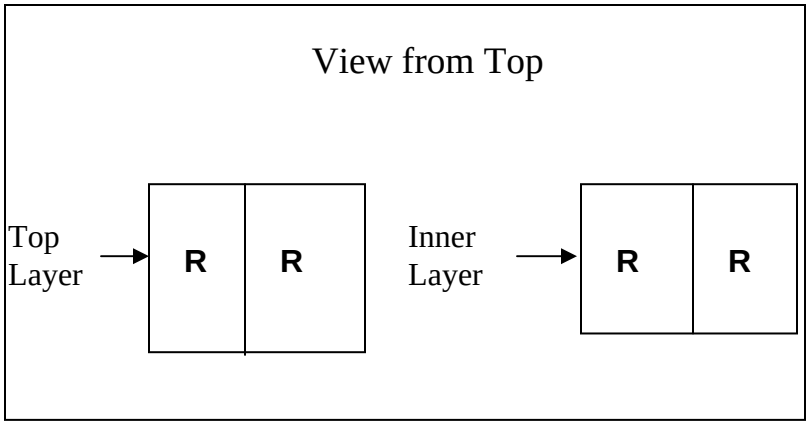


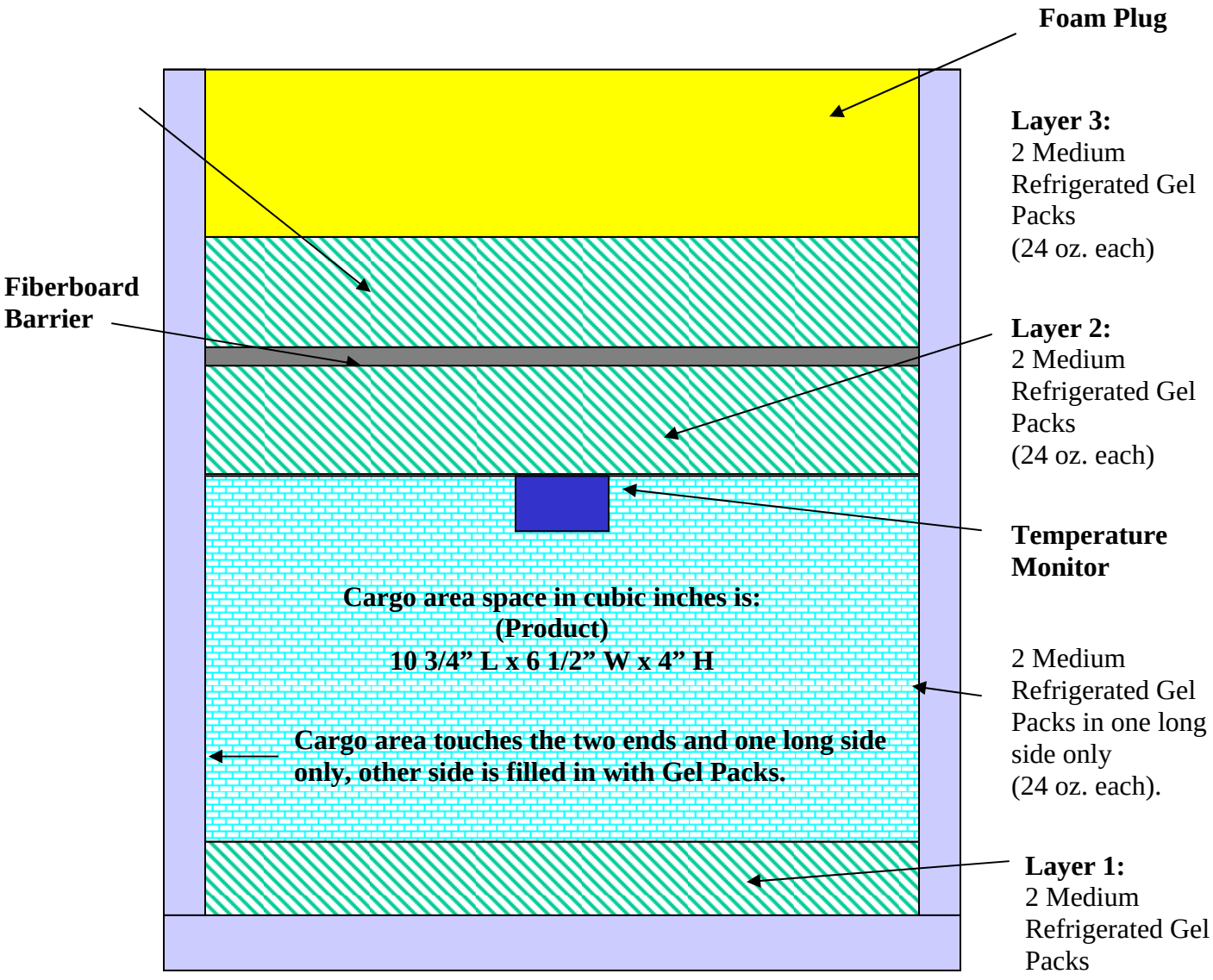
Side View

Small (ISC Box E-36-2) – Cold Weather Packing Protocol Diagram

Box Outer Dimensions:
15-1/2" x 12" x 14"
Refrigerant Pack Weight: 12 lbs
See attachment 3 for additional information.

Total amount of chilled Gel Packs = 8
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs





Side View

Moderate Weather Packaging Protocol

- Moderate Weather Configuration is used when the ambient temperature **at the receiving site** is between 55° F and 77° F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2° C and 8° C (36^{o} F and 46^{o} F) within these temperature ranges during transportation, for up to 72 hours.
- 48 oz. and 24 oz. gel packs are used in all boxes for layering and void space filler.
- Coolant material must be placed in layers according to attached diagrams. Moderate configuration uses a combination of refrigerated and frozen gel packs. **Frozen gel packs are always farthest away from vaccine**.

Moderate Weather Packaging Protocol Procedures

The Moderate Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is between 55 degrees Fahrenheit and 77 degrees Fahrenheit. Begin the Moderate Weather packing protocol by:

- Placing a layer of refrigerated gel packs at the bottom of the box.
- Next item will be the product.
- Place gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.
- This is followed by placing an activated TempTale®4 electronic temperature monitor on top of the product. Activate the TempTale®4 temperature monitor by pressing and releasing the "start" button. Once the button is released, a "sunshine" icon will appear in the upper left corner of the LCD. This indicates that the monitor is running. Peel off the tape in the back of the TempTale®4 and place it centered on top of the product.
- Follow with another layer of refrigerated gel packs.
- Above the second layer of refrigerated gel packs insert a fiberboard barrier.
- Add a final layer of a combination of refrigerated and frozen gel packs above the fiberboard barrier.
- Finally, insert the foam plug to seal the contents of the box.

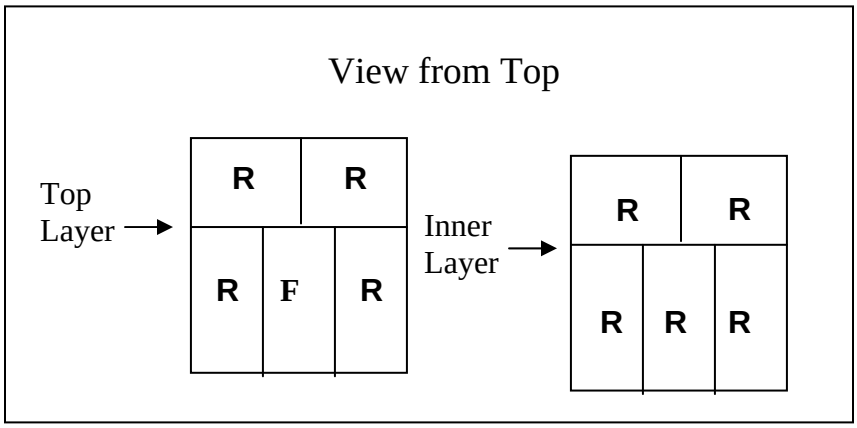
Notes:

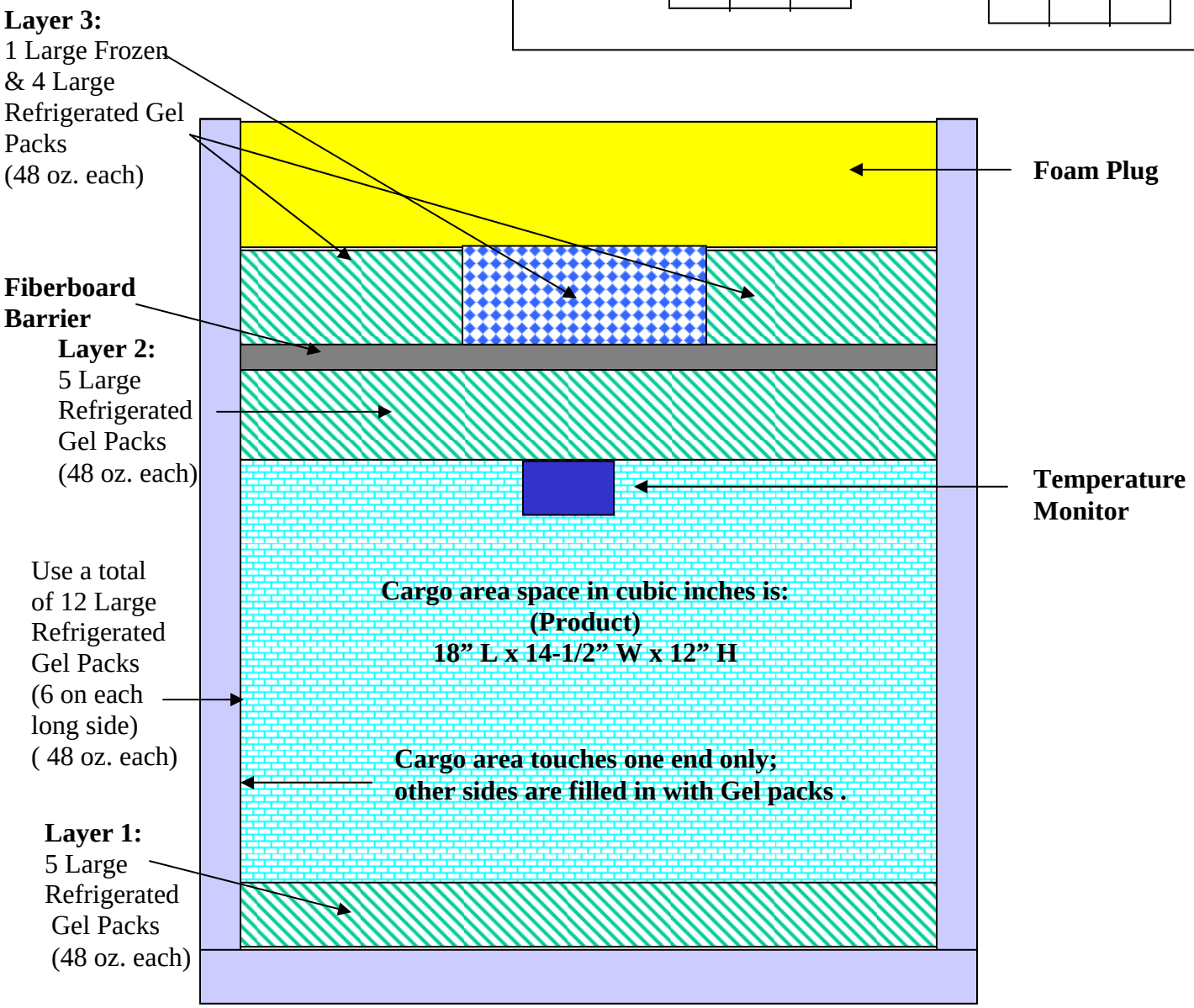
1. Follow procedures according to each protocol diagram of ISC Endurotherm® box used.
2. To chill large amounts of gel packs at once, place gel pack boxes inside a refrigerator that has been set to 4° C for at least 30 days prior to use.
3. To quickly chill small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior use.
4. To freeze large amounts of gel packs at once, place gel pack boxes inside a freezer that has been set to -17°C for at least 30 days prior use.
5. To quickly freeze small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

Extra Large (ISC Box, E-327) – Moderate Weather Packaging Protocols Diagram

Box Outer Dimensions: 24" x 24" x 24"
Refrigerant Pack Weight: 81 lbs
See attachment 3 for additional information.

Total amount of Gel Packs:
Chilled = 26
Frozen = 1
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



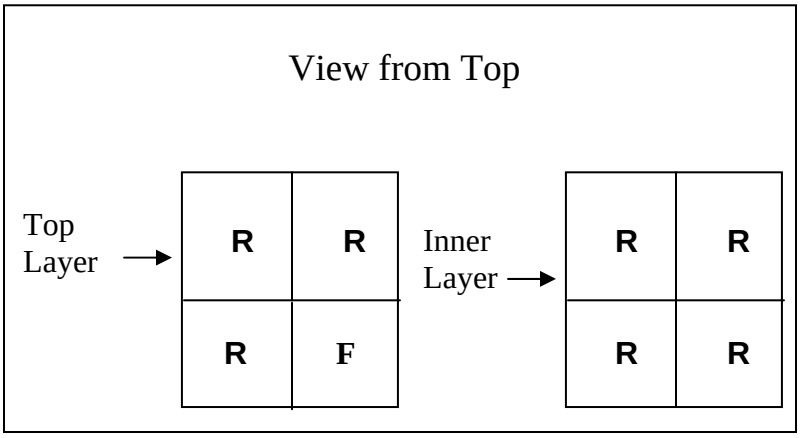


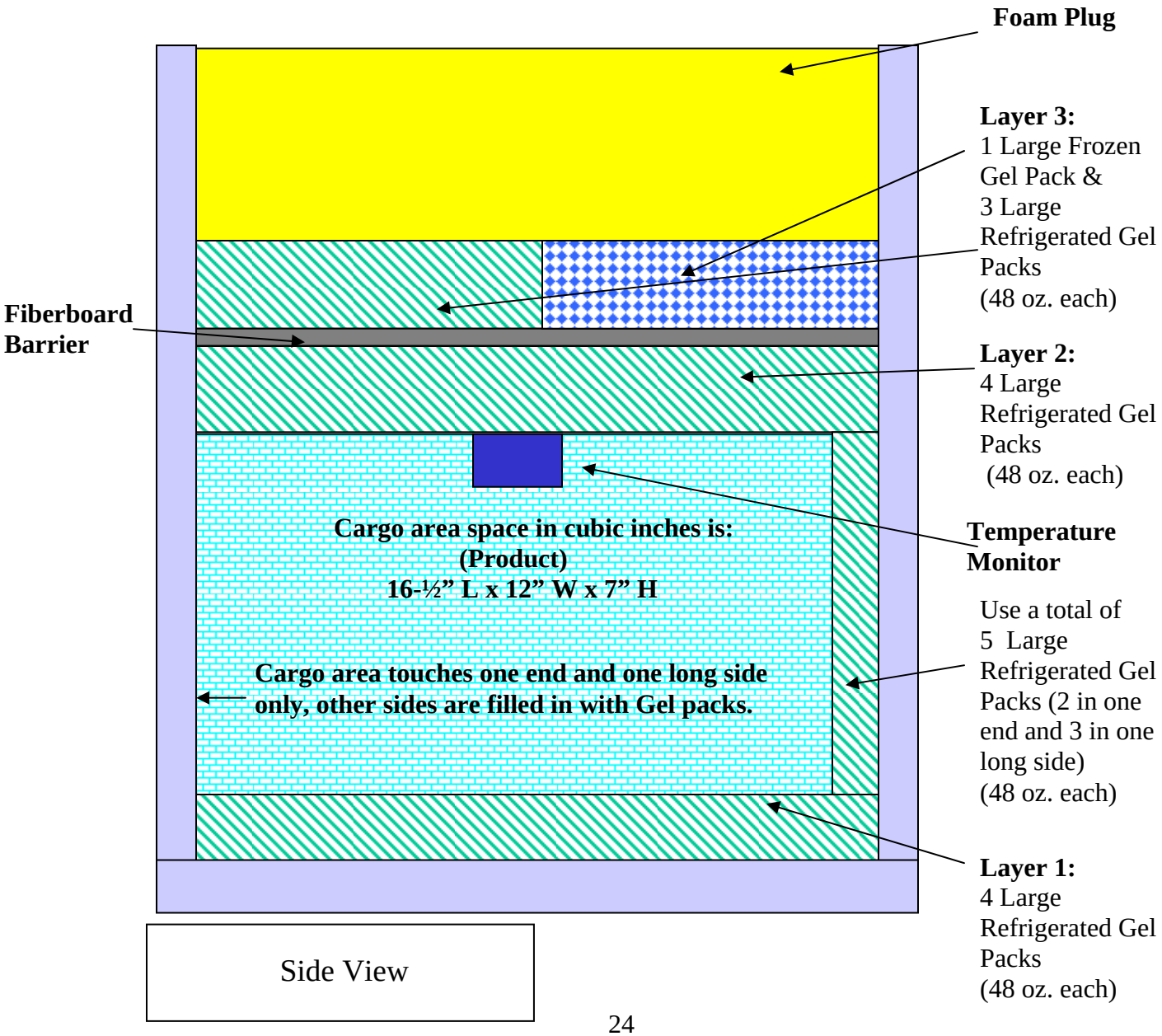
Side View

Large (ISC Box, E-186) – Moderate Weather Packaging Protocols Diagram

Box Outer Dimensions:
22-1/2" x 19" x 17-1/2"
Refrigerant Pack Weight: 51 lbs
See attachment 3 for additional information.

Total amount of Gel Packs:
Chilled = 16
Frozen = 1
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs



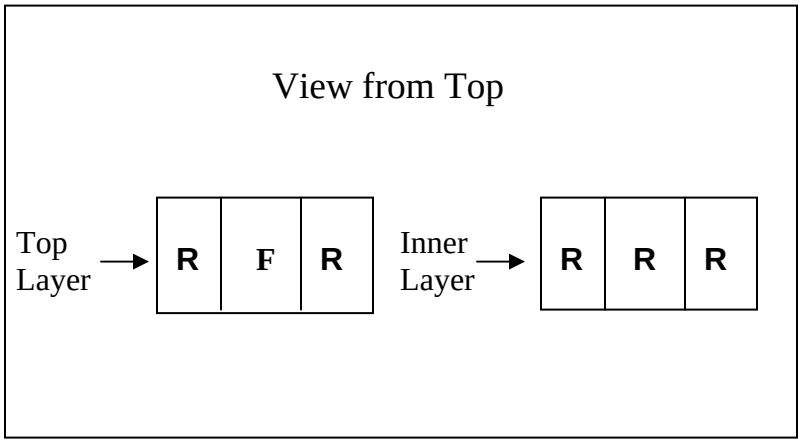


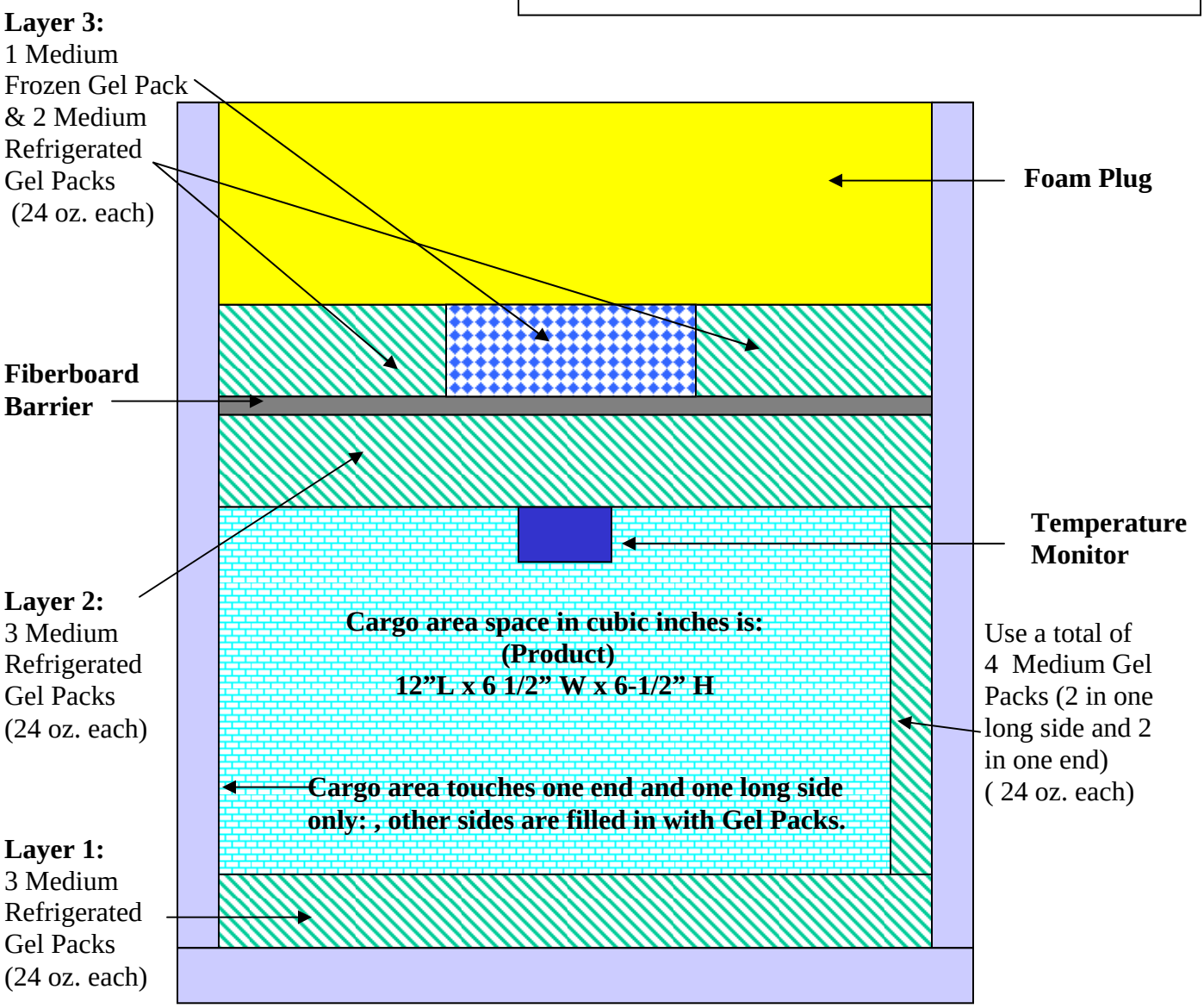
Side View

Medium (ISC Box, E-65) – Moderate Weather Packaging Protocols Diagram

Box Outer Dimensions: 18" x 12" 18"
Refrigerant Pack Weight: 19-1/2 lbs
See attachment 3 for additional information.

Total amount of Gel Packs = 13
Chilled = 12
Frozen = 1
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs



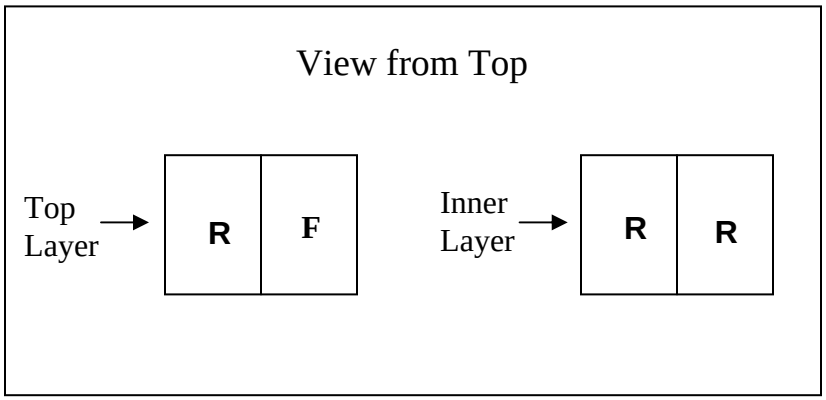


Side View

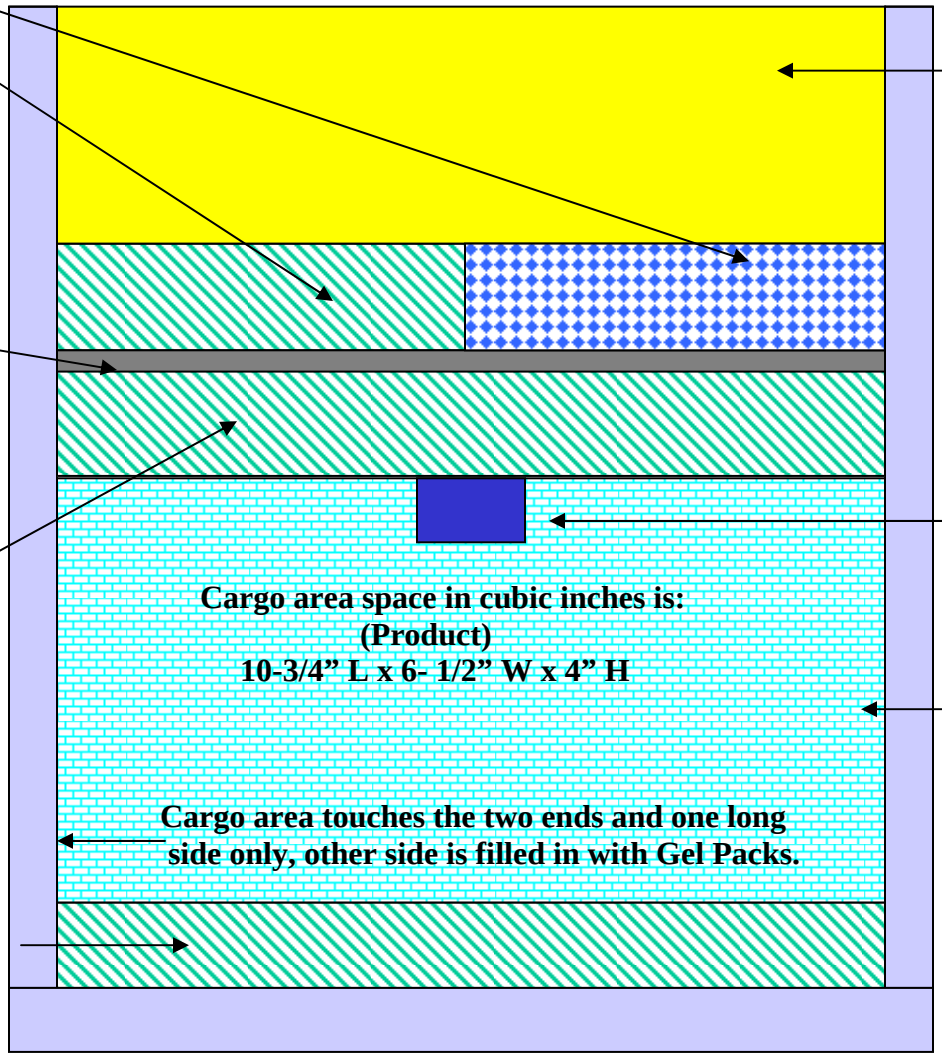
Small (ISC Box E-36-2) – Moderate Weather Packaging Protocols Diagram

Box Outer Dimensions:
15-1/2" x 12" x 14"
Refrigerant Pack Weight: 12 lbs
See attachment 3 for additional information.

Total amount of Gel Packs = 8
Chilled = 7
Frozen = 1
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs



Layer 3:
1 Medium Frozen Gel Pack &
1 Medium Refrigerated Gel Pack
(24 oz. each)



Layer 2:
2 Medium Refrigerated Gel Packs
(24 oz. each)

2 Medium Refrigerated Gel Packs in one long side only
(24 oz. each).

Layer 1:
2 Medium Refrigerated Gel Packs
(24 oz. each)

Side View

Warm Weather Packaging Protocol

- Warm Weather Configuration is used when the ambient temperature **at the receiving site** is consistently above 77° F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2° C to 8° C (36^{o} F and 46^{o} F) within these temperature ranges during transportation, for up to 72 hours.
- 48 oz. and 24 oz. gel packs are used in all boxes for layering and void space filler.
- Coolant material must be placed in layers according to attached diagrams. Warm weather configuration uses a combination of refrigerated and frozen gel packs. **Frozen gel packs are always farthest away from vaccine**.

Warm Weather Packaging Protocol Procedures

The Warm Weather Packaging Protocol is used whenever the ambient or outside temperature at the receiving site is consistently above 77 degrees Fahrenheit. Begin the warm weather packing protocol by:

- Placing a layer of refrigerated gel packs at the bottom of the box.
- Next item will be the product.
- Place gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.
- This is followed by placing an activated TempTale®4 electronic temperature monitor on top of the product. Activate the TempTale®4 temperature monitor by pressing and releasing the "start" button. Once the button is released, a "sunshine" icon will appear in the upper left corner of the LCD. This indicates that the monitor is running. Peel off the tape in the back of the TempTale®4 and place it centered on top of the product.
- Follow with another layer(s) of refrigerated gel packs.
- Above the second layer of refrigerated gel packs insert a fiberboard barrier.
- Add a final layer of a combination of refrigerated and frozen gel packs above the fiberboard barrier.
- Finally, insert the foam plug to seal the contents of the box.

Notes:

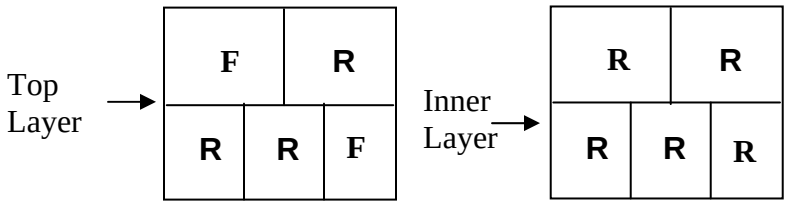
1. Follow procedures according to each protocol diagram of ISC box used.
2. To chill large amounts of gel packs at once, place gel pack boxes inside a refrigerator that has been set to 4° C for at least 30 days prior to use.
3. To quickly chill small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior use.
4. To freeze large amounts of gel packs at once, place gel pack boxes inside a freezer that has been set to -17°C for at least 30 days prior use.
5. To quickly freeze small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

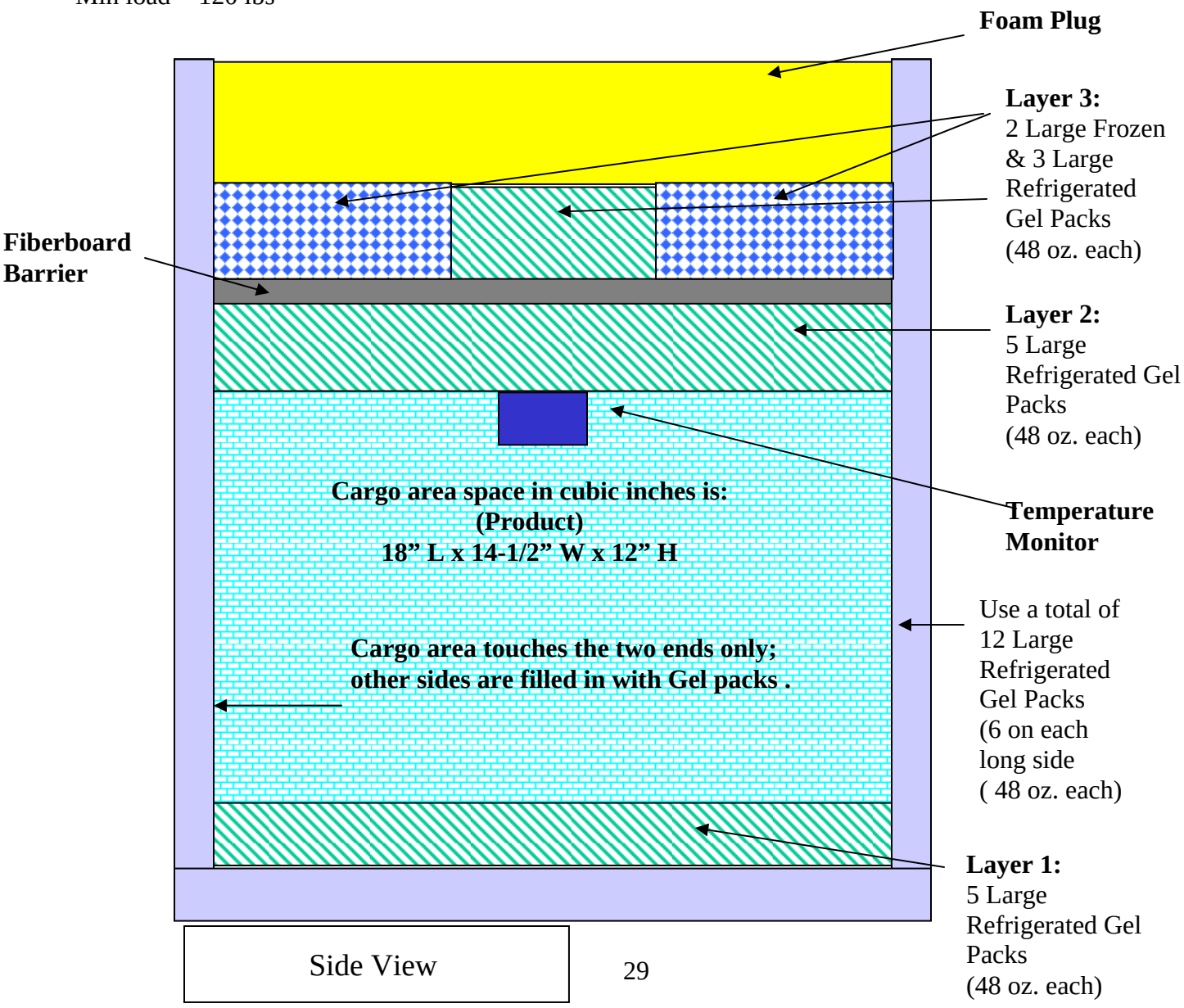
Extra Large (ISC Box, E-327) – Warm Weather Packaging Protocol Diagram

Box Outer Dimensions:
24" x 24" x 24"
Refrigerant Pack Weight: 81 lbs
See attachment 3 for additional information.

Total amount of Gel Packs = 27
Chilled = 25
Frozen = 2
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs

View from Top





Side View

Large (ISC Box, E-186) – Warm Weather Packaging Protocol Diagram

Box Outer Dimensions:
22-1/2" x 19" x 17-1/2"
Refrigerant Pack Weight: 51 lbs
See attachment 3 for additional information.

Total amount of Gel Packs:
Chilled = 15
Frozen = 2
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs

View from Top

Top Layer → | F | R |
| R | F |

Inner Layer → | R | R |
| R | R |

Layer 3:
2 Large Frozen Gel Packs &
2 Large Refrigerated Gel Packs
(48 oz. each)

Foam Plug

Fiberboard Barrier

Temperature Monitor

Layer 2:
4 Large Refrigerated Gel Packs
(48 oz. each)

Cargo area space in cubic inches is:
(Product)
16-1/2" L x 12" W x 7" H

Cargo area touches one end and one long side only,

Use a total of 5 Large Refrigerated Gel Packs
(2 in one end and 3 in one long side)
(48 oz. each)

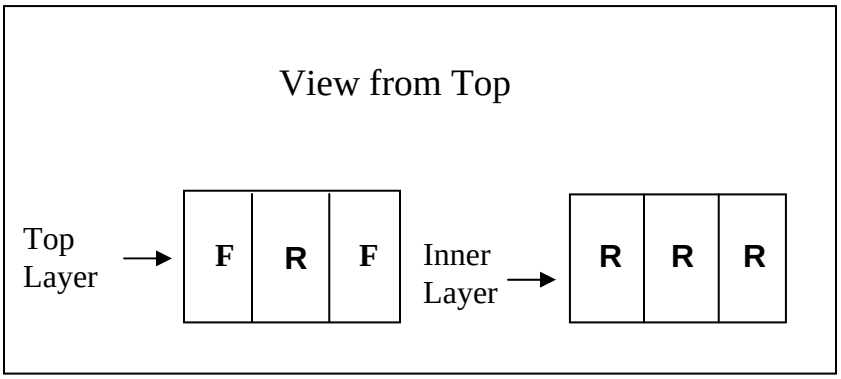
Layer 1:
4 Large Refrigerated Gel Packs
(48 oz. each)

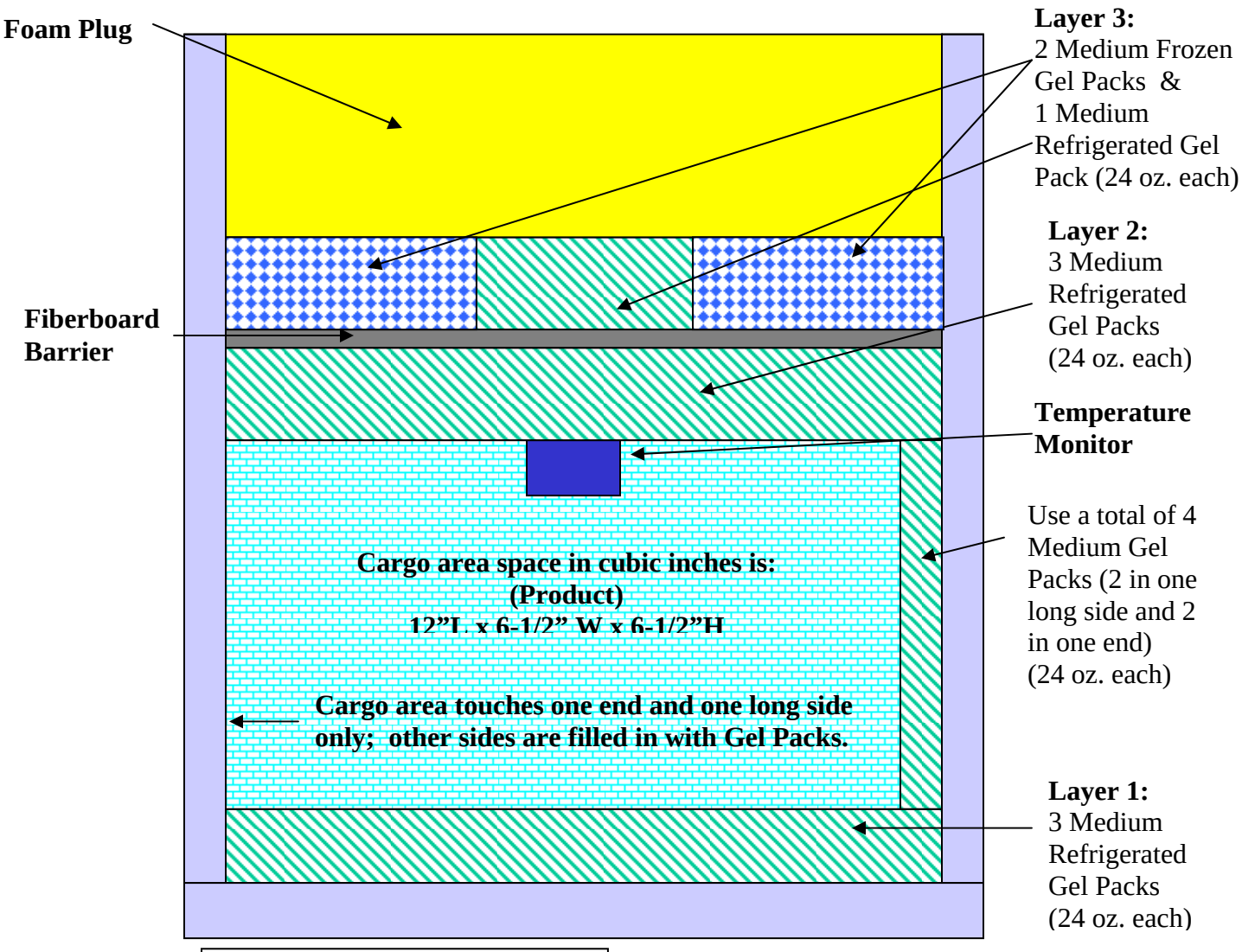
Side View

Medium (ISC Box, E-65) – Warm Weather Packaging Protocol Diagram

Box Outer Dimensions: 18" x 12" x 18"
Refrigerant Pack Weight: 19-1/2 lbs
See attachment 3 for additional information.

Total amount of Gel Packs = 13
Chilled = 11
Frozen =2
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs



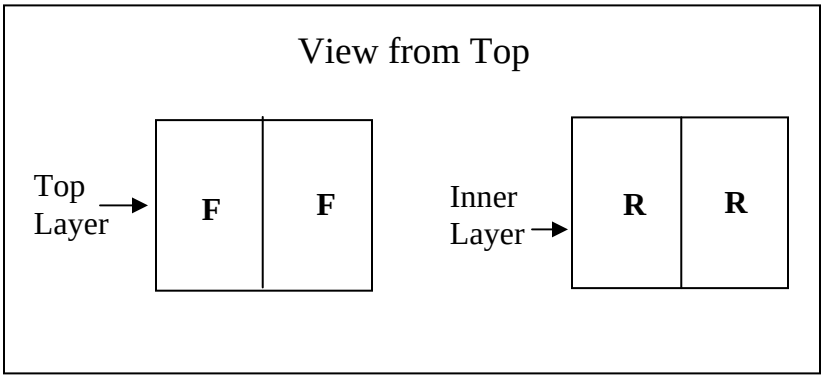


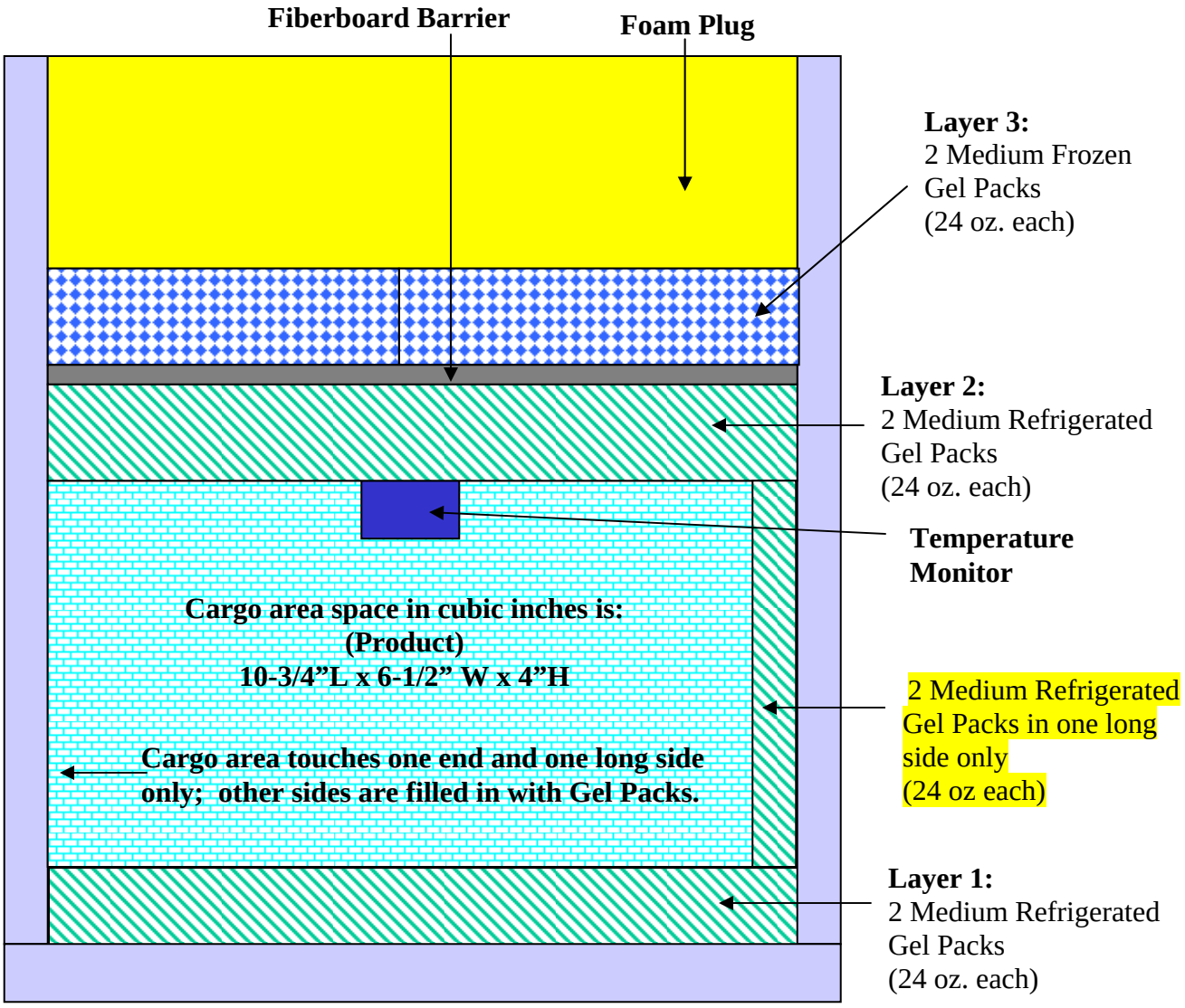
Side View

Small (ISC Box E-36-2) – Warm Weather Packing Protocol Diagram

Box Outer Dimensions:
15-1/2" x 12" x 14"
Refrigerant Pack Weight: 12 lbs
See attachment 3 for additional information.

Total amount of Gel Packs = 8
Chilled = 6
Frozen = 2
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs





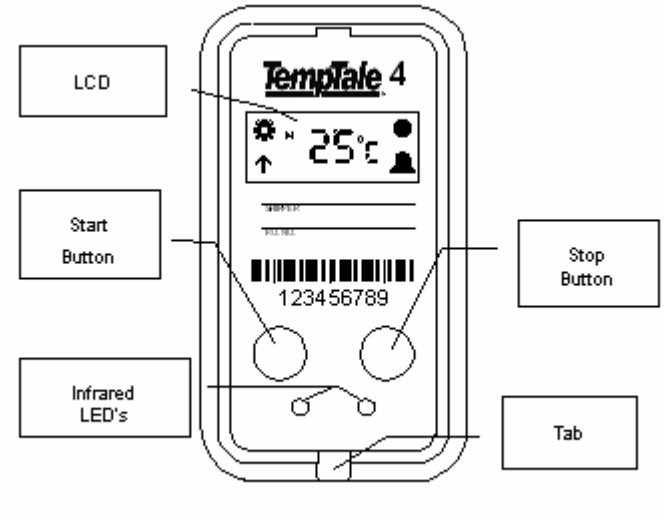
Side View

Starting a TempTale®4 Monitor

Hold down the **start** button (**the green button on the monitor**) until you see the sunshine icon (picture) on the upper left corner of the LCD that confirms that the monitor has started.

When the monitor is activated, the sunshine icon will stay on until the monitor has been stopped.

The monitor will begin recording data after the startup delay is completed.



Instructions for Reading a TempTale®4 LCD

Press the **start** button. Five pieces of information will scroll, always in this order:

· Average temperature during the entire recording cycle

· Highest Temperature reached during the recording cycle

· Cumulative amount of time above the high temperature alarm

· Lowest Temperature reached during the recording cycle

· Cumulative amount of time below the low temperature alarm